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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/681,508	04/18/2001	Yun Lin	NEX 89	4609

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EXAMINER	
ZITOMER, STEPHANIE W	
ART UNIT	**PAPER NUMBER**
1634	12

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/681,508	Applicant(s) LIN et al.
	Examiner S. Zitomer	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 13, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *29-60* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *29-60* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Apr 18, 2001* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Application status

1. Receipt of the amendment filed August 13, 2002 is acknowledged.

2. All rejections of claims 1-28 set forth in the previous Office action, paper no. 9 mailed May 8, 2002, have been withdrawn in view of cancelation of the said claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejection under 35 U.S.C. 102(e): Anticipation

3. Claims 29-36, 8-13, 15-20, 22-27 and 29 are rejected under 35 U.S.C. 102(e) as being unpatentable over the patent to Gold et al. (6,242,246). The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Regarding claims 29 and 45, the claimed invention method comprising a) binding two or more target molecules in a substance to two or more capture molecules which is immobilized on a solid support thereby forming a capture molecule:target molecule complex; b) removing unbound substance; c) binding a reporter molecule to the target molecule thereby forming a capture molecule:target molecule:reporter molecule complex; d) detecting the complexes, wherein the capture molecule, reporter molecule or both are a nucleic acid ligand to the target molecule is disclosed at column 10, lines 41-47 and 63-66. The method of claim 45 is the same as that of claim 29 except wherein both the capture molecule and reporter molecule are nucleic acid ligands to the target compound and with the addition of steps for identifying a nucleic acid ligand to the target compound by the SELEX process. The latter is disclosed at column 1, lines 34-49. Regarding claims 30-32 and 46-48, the reporter molecule is disclosed as a detection system which is a nucleic acid ligand labeled with a fluorophore which is fluorescein at column 10, lines 62-67; column 11, line 48. Regarding claims 34 and 50, the solid support is disclosed as a membrane at column 9, lines 3-7. Regarding claims 36, 38-41, 52 and 54-57, the claimed method is

disclosed at column 10 wherein the target molecule is a protein (line 34); wherein the capture and reporter molecules are nucleic acid ligands that bind to non-overlapping sites in the target molecule (lines 62-66); wherein the capture molecule is a nucleic acid ligand and the reporter molecule is a protein (lines 44-47); and wherein the reporter binds to a site on the capture molecule:target molecule complex (lines 34-68; column 11 at B.). Regarding claims 37 and 53 wherein the target protein is thrombin is disclosed at column 7, lines 52-59. Regarding claims 32, 33, 58 and 59, the method wherein the substance is a biological fluid which may be plasma or urine is disclosed at column 6 at 7. Regarding claim , the method is the same as that of claim 1 except that the presence of two or more target compounds is detected. This method is disclosed at column 2, lines 39-42, column 6 at 8. and column 8, lines 41-46.

Rejections under 35 U.S.C. 103(a): Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 29-37, 45-52 and 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable WO 96/41019 in view of Gold et al. (6,242,246). Regarding claims 29, 33, 34, 44, 45 and 60, the claimed invention method comprising a) binding a target molecule in a substance to a capture molecule which is immobilized on a particulate solid support

thereby forming a capture molecule:target molecule complex; b) removing unbound substance, i.e., washing; c) binding a reporter molecule to the target molecule thereby forming a capture molecule:target molecule:reporter molecule complex; d) detecting the complex by flow cytometry, wherein the capture molecule, reporter molecule or both are a nucleic acid ligand to the target molecule is disclosed at page 7, lines 1-13, page 13, lines 14-23, page 31, claim 13 and page 16, lines 13-14. The claimed invention method differs from that of the reference wherein two or more target compounds are detected in a substance which may contain them. However, multiplex assays were routinely practiced in the art as exemplified with nucleic acid ligands by the biochip of Gold et al. and the skilled practitioner in the art would have been motivated to detect two or more target compounds in the reference assay for the obvious benefit of obtaining additional information in the expanded assay. Regarding claims 35 and 51 wherein the solid support is comprised of a spatially addressable array, The method of claim 45 is the same as that of claim 29 except wherein both the capture molecule and reporter molecule are nucleic acid ligands to the target compound and with the addition of steps for identifying a nucleic acid ligand to the target compound by the SELEX process. The former is disclosed at page 14, lines 4-6 and the latter at pages 8-9. Regarding claims 30-32 and 16-18, the fluoresceinated nucleic acid ligand detection system is disclosed at page 16, line 11. Regarding claims 36, 37 and 52, the protein target molecule is disclosed as L-selectin at page 22, line 6. Regarding claims 38 and 54, the method wherein the capture and reporter molecules are nucleic acid ligands is disclosed at page 14, lines 4-6. Regarding claims 42, 43, 58 and 59, the method wherein the substance is a biological fluid which may be selected from plasma or urine is disclosed at page 4, lines 23-24.

5. Claims 29-31, 36, 38, 42, 43, 45-48, 52, 54, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/40991 in view of Gold et al. (6,2452,246). Regarding claims 29, 38, 45 and 54 the claimed invention method comprising a) binding a target molecule in a substance to a capture molecule which is immobilized on a solid support thereby forming a capture molecule:target molecule complex; b) removing unbound substance; c) binding a reporter molecule to the target molecule thereby forming a capture molecule:target molecule:reporter molecule complex; d) detecting

the complexes, wherein the capture molecule, reporter molecule or both are a nucleic acid ligand to the target molecule is disclosed at page 24, claim 5. The claimed invention method differs from that of the reference wherein two or more target compounds are detected in a substance which may contain them. However, multiplex assays were routinely practiced in the art as exemplified with nucleic acid ligands by the biochip of Gold et al. and the skilled practitioner in the art would have been motivated to detect two or more target compounds in the reference assay for the obvious benefit of obtaining additional information in the expanded assay. The method of claim 45 is the same as that of claim 29 with the addition of steps for identifying a nucleic acid ligand to the target compound by the SELEX process. The latter is disclosed at page 25-26, claim 13. Regarding claims 30-32 and 46-48, the reporter molecule is disclosed as a detection system which is a nucleic acid ligand labeled with a fluorophore at page 12, lines 15-20 wherein the latter is fluorescein at page 10, lines 22-23. Regarding claim 6 and 20, the protein target molecule is disclosed at page 24, claim 6. Regarding claims 42, 43, 58 and 59, the method wherein the substance is a biological fluid which may be plasma or urine is disclosed at page 13, lines 12-13.

Conclusion

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

S Zitomer

Stephanie Zitomer, Ph.D.

November 18, 2002

STEPHANIE W. ZITOMER
PRIMARY EXAMINER